

REMARKS

Claims 35, 36, 38-40, 42-49, and 56-67 were pending in the application. Claims 38, 42, and 58-61 have been cancelled. Claims 35, 39, 62-63, and 65-67 have been amended. New claim 68 has been added. Accordingly, following entry of the amendments presented herein, claims 35-36, 39-40, 43-49, 56-57, and 62-68 will be pending.

No new matter has been added. Support for the amendments presented herein can be found in the specification as filed and/or the claims as previously pending. Specifically, support for the amendments to claim 35 can be found at least at page 5, lines 20-24, and page 8, lines 9-11 and the claims as previously pending and examined. Support for new claim 68 can be found at least at page 37, lines 3-8 and the term “regulatory sequence of the IL-4 gene” has previously been examined.

Cancellation of and/or amendments to the claims should in no way be construed as acquiescence to any of the Examiner's rejections and were done solely to expedite prosecution of the above-identified application. Applicants reserve the option to further prosecute the same or similar claims in the instant or in another patent application(s).

No additional search is required and no new issues have been raised by the amendments made herein; support for the amendments made can be found in the specification as filed and/or in the claims as previously pending. Furthermore, in view of the amendments and arguments set forth herein, the number of issues for appeal have been reduced. It is believed that the Examiner's rejections under §112, first and paragraph have been obviated by claim amendments and cancellations. Therefore, the claim amendments and cancellations made herein are permissible under 37 C.F.R. §1.116 as reducing the number of issues for appeal, and Applicants respectfully request that the present Amendment be entered.

Withdrawal of Rejection of Claims 35, 37-39, and 41-49***Under 35 U.S.C. § 112, Second Paragraph***

Applicants thank the Examiner for the withdrawal of the rejection of claims 35, 37-39, and 41-49 under 35 U.S.C. §112, second paragraph.

Rejection of Claims 35-36, 38-40, 42-49, and 56-57***Under 35 U.S.C. § 112, First Paragraph***

The Examiner has rejected claims 35-36, 38-40, 42-49, and 56-57 under 35 U.S.C. §112, first paragraph. Specifically, the Examiner states that the cited passages for support of the amendments filed 9/11/03 are “specific for c-maf binding to the MARE sequence linked to the IL-4 gene and merely provide support for c-maf binding to the MARE sequence associated with the IL-4 gene. The cited passages do not provide support for the concept of a broad range of maf family proteins that bind to a MARE sequence obtained from a Th2-associated gene”. “In addition the rejected claims encompass embodiments wherein the maf family protein must possess the ability to bind a MARE sequence of a Th2-associated cytokine gene”. “The prior art and specification do not provide a structural/functional basis for the skilled artisan to envision embodiments wherein a” maf family protein is other than c-maf or v-maf.

The Examiner has also rejected claims 35-36, 38-40, 42-49, and 56-67 under 35 U.S.C. §112, first paragraph, “because the specification, while being enabling for embodiments wherein the MARE sequence is the MARE regulatory sequence of the interleukin-4 gene and wherein the maf family protein is c-maf, does not reasonably provide enablement for practicing the claimed invention with any other combination of MARE element and maf family protein.”

This rejection is respectfully traversed. Applicants reiterate their position that enablement is not precluded by the necessity for some experimentation, and a considerable amount of experimentation is permitted. See In re Wands, 8 U.S.P.Q. 2d 1400, 1404 (Fed. Cir. 1988). It is Applicants’ position that based on the teachings of the specification and the knowledge in the art, the ordinarily skilled artisan would be able to make and use the claimed methods without undue experimentation.

More specifically, maf family proteins that bind to a MARE responsive element could readily be identified by one of ordinary skill in the art (*e.g.*, as described at page 7, line 32 through page 8, line 1 of the specification). While the working examples of the instant application focus on c-maf, other maf family proteins were known to be structurally similar to c-maf. For example, v-maf was known in the art to be structurally similar to c-maf, having only two structural changes in the coding region from c-maf (a substitution of an M residue at position 257 to V and fusion of the viral gag sequence to the 5' terminal end; see Kataoka *et al.* 1993. *J. Virol.* 67:2133). The ability of a maf family protein to bind to a MARE responsive element or a Th2-associated cytokine gene could be tested using the methods as described in Example 6 or using other techniques well known in the art. Based on the teachings of the specification, one of ordinary skill in the art could readily select maf family proteins within the scope of the claims based on their ability to bind to a MARE responsive element of a Th2-associated cytokine gene.

With respect to the Th2 associated cytokine gene, the claims require that the target DNA comprise a MARE regulatory sequence of a Th2-associated cytokine gene. MARE regulatory elements and their structure are taught in the specification. For example, Applicants teach that MARE responsive elements are known in the art and include the 13 or 14 base pair elements which contain a core TRE (T-MARE) or CRE (C-MARE) palindrome (see page 8, lines 9-11). Applicants further show the existence of a MARE response element in the promoter region of IL-4 (see Example 6). Applicants note that c-maf has been shown to activate IL-10 transcription as well as IL-4 transcription (see, *e.g.*, the paper by Cao *et al.* ((2002) *J. Immunol.* 169:5715-25). Based on the teachings in the specification and the knowledge of one of ordinary skill in the art, the ordinary skilled artisan could readily select a target gene within the scope of the claims.

With respect to the production of Th2 cytokines, as taught in the specification, *e.g.*, at page 8 lines 31-37, and as known in the art, an effect of a compound on Th2 cytokine production, *e.g.*, IL-4 or IL-10, could be measured either directly by measuring production of IL-4 or IL-10, or indirectly by measuring production of other Th2 cytokines. One of ordinary skill in the art could readily measure Th2 cytokines using

techniques described in the specification or known in the art. Exemplary techniques are taught at page 37, lines 35-39 and at pages 40, line 34 through page 41, line 4 of the specification.

As set forth above, Applicants have described a genus of maf family proteins and MARE responsive elements. Applicants have provided description of a variety of exemplary species to reflect the variation within the genus of maf family proteins (*e.g.*, at page 7, line 24 through page 8, line 1 of the specification) and MARE responsive elements. Thus, structural information regarding the maf family of proteins and MARE elements to which they bind is taught in the specification and was known in the art at the time the application was filed. Therefore, the instant specification satisfies the written description requirement for the claimed invention as set forth in the Written Description Guidelines (66 Fed. Reg at 1106) and by the court in *Enzo Biochem, Inc. v. Gen-Probe Inc.* (296 F.3d 1316 (Fed. Cir. 2002)).

However, in the interest of expediting prosecution of the application, while in no way conceding to the Examiner's rejection, Applicants have amended claim 35 to specifically recite that the indicator composition comprises *c-maf or v-maf* and a ***regulatory sequence of an IL-4 gene which includes a c-maf responsive element (MARE)***.

In view of the foregoing, Applicants respectfully request that the Examiner reconsider and withdraw the foregoing rejections of claims 35-36, 38-40, 42-49, and 56-57 under 35 U.S.C. §112, first paragraph.

CONCLUSION

Reconsideration and allowance of all the pending claims is respectfully requested. If a telephone conversation with Applicants' Attorney would expedite prosecution of the above-identified application, the Examiner is urged to call the undersigned at (617) 227-7400.

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